



UNITED STATES PATENT AND TRADEMARK OFFICE

44

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/652,799 | 08/29/2003 | Barry Eisenstein | 50150/005003 | 2013 |

21559 7590 08/25/2006

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/652,799 | Applicant(s) EISENSTEIN, BARRY | |
| | Examiner Blessing M. Fubara | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 35-44, 46-48 and 51-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 35-44, 46-48 and 51-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9/1/05 & 9/26/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1618.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, request for reconsideration and remarks, all filed 10/21/04. Examiner further acknowledges the receipt of IDS filed 01/13/05. Claims 1-10, 12, 35-44, 46-48 and 51-53 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-10, 12, 35-44, 46-48 and 51-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The specification as originally filed does not support the scope of the presently claimed composition of the claims. The specification at paragraphs [000], [0011], and Example 1 supports oral, rectal, intravenous and subcutaneous administration. The specific composition limited by the consisting language now recited in the claims is not envisioned. There is nothing in the specification pointing to this specific administration where riflazil is administered only by rectal or oral.

Applicant may overcome this rejection by amending the claims to be commensurate with the administration methods disclosed in the specification.

The rejection of claims 1-10, 12, 35-44, 46-48 and 51-53 under scope of enablement is withdrawn in view of the cancellation of claims and amendment.

The rejection of claims 54-75 under 35 USC 101 is withdrawn in view of the cancellation claims 54-75.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-10, 25-44 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Michaelis et al. (US 2004/0034021).

1-10, 12, 35-44, 46-48 and 51-53

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Michaelis discloses method of treating infection of clostridium difficile by administering composition that comprises rifalazil; the composition that is administered may further contain one or more antibiotics (paragraphs [0013], [0014], [0054], [0114], [0115], [0124], [0145], and claims 1-62). Michaelis does not exclude oral administration except that Michaelis preferred using

Art Unit: 1618

parenteral administration when treating many nosocomial and serious community acquired infections (paragraph [0083]). This paragraph does not point to exclusionary use of parenteral administration.

Response to Arguments

5. Applicant's arguments filed 6/5/06 have been fully considered but they are not persuasive.

Regarding oral or rectal administration in the instant case vs. Michaelis, it is noted that Michaelis does not exclude oral or rectal administration.

Claim Rejections - 35 USC § 103

6. The rejection of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over Chamberland et al. (US 6,114,310) in combination with Rose et al. (US 6,316,433) is withdrawn in view of applicant's argument as it relates to the amended claims. However, this rejection may be reinstated once the new matter rejection is overcome and the claims read of the combined teaching of Chamberland and Rose.

7. The rejection of claims 35, and 37-44 and 53 under 35 U.S.C. 103(a) as being unpatentable over Chamberland et al. (US 6,114,310) in combination with Rose et al. (US 6,316,433) in further combination with Bostwick et al. (US 5,773,000) is withdrawn in view of applicant's argument as it relates to the amended claims. However, this rejection may be reinstated once the new matter rejection is overcome and the claims read of the combined teaching of Chamberland and Rose in view of Bostwick.

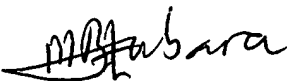
Art Unit: 1618

8. The rejection of claim 12 under 35 U.S.C. 103(a) as being unpatentable over Chamberland et al. (US 6,114,310) in combination with Rose et al. (US 6,316,433) in further combination with the admission of applicant in the specification is withdrawn in view of applicant's argument as it relates to the amended claims. However, this rejection may be reinstated once the new matter rejection is overcome and the claims read of the combined teaching of Chamberland and Rose in further combination with applicants admitted prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Blessing Fubara
Patent Examiner
Tech. Center 1600